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May 21, 1992

National Toxicology Program; Chemicals (10) Nominated for Toxicological Studies; Request for Comments

SUMMARY: The **National Toxicology Program (NTP)** is soliciting public comments on ten chemicals nominated for toxicological studies. These comments will assist the NTP in making informed decisions about whether to perform toxicological testing of these chemicals.

FOR FURTHER INFORMATION CONTACT: Dr. Victor A. Fung, Chemical Selection Coordinator, **National Toxicology Program**, room B1C02, Building 31, National Institutes of Health, Bethesda, Maryland 20892, (301) 496-3511.

TEXT: SUPPLEMENTARY INFORMATION: The NTP Chemical Evaluation Committee (CEC) is composed of representatives from the agencies participating in the NTP. As part of the chemical selection process of the National Toxicology Program, nominated chemicals which have been reviewed by the CEC are published in the Federal Register with request for comment. The purpose is to encourage active participation in the NTP chemical evaluation process, thereby helping the NTP to make more informed decisions as to whether to select, defer or reject chemicals for toxicology study. Comments and data submitted in response to this announcement will be reviewed by NTP technical staff for use in the further evaluation of the nominated chemicals. The NTP chemical nomination and selection process is summarized in the Federal Register, April 1981 (46 FR 21828) and also in the NTP FY 1991 Annual Plan, pages 17-19.

On March 5, 1992, the CEC met to evaluate ten chemicals nominated to the NTP for toxicological studies. The following table lists the chemicals, their Chemical Abstract Service (CAS) registry numbers, and the types of toxicological studies recommended by the CEC.

Chemical	CAS registry No.	Committee recommendations
1. Chloral hydrate	302-17-0	Carcinogenicity. Mechanistic studies.
2. 2-Cyclohexen-1-one	930-68-7	Carcinogenicity.
3. Ethyl cyanoacrylate	7085-85-0	Carcinogenicity. Reproductive and developmental effects. Neurotoxicity.
4. Ethyl vinyl ketone	1629-58-9	Toxicity. Mutagenicity.
5. Lidocaine	137-58-6	No testing.
6. 2-Methylimidazole	693-98-1	Carcinogenicity.
7. 4-Methylimidazole	822-36-6	Carcinogenicity.
8. Methyl vinyl ketone	78-94-4	Carcinogenicity.
9. Prednisone	53-03-2	No testing.
10. Trimethoprim/Sulfamethoxazole	8064-90-2	Carcinogenicity. Neurotoxicity.

NTP has previously performed genotoxicity studies on three of the chemicals. Chloral hydrate was mutagenic in *Salmonella*, induced chromosomal aberrations and sister chromatid exchanges in Chinese hamster ovary (CHO) cells, and gave equivocal results for sex-linked recessive lethal mutations in *Drosophila*. Methyl vinyl ketone was mutagenic in *Salmonella*. Prednisone was mutagenic in *Salmonella* in one study and non-mutagenic in another study.

In addition, NTP has tested the individual components of the Trimethoprim (TMP)/Sulfamethoxazole (SMX) mixture. TMP was nonmutagenic in *Salmonella*, weakly positive for chromosomal aberrations in one study and negative in another study in CHO cells; positive and weakly positive for sister chromatid exchanges in CHO cells in two independent studies. Sulfamethoxazole was nonmutagenic in *Salmonella*.

Interested parties are requested to submit pertinent information on all of the nominated chemicals. The following types of data are of particular relevance:

- (1) Modes of production, present production levels, and occupational exposure potential;
- (2) Uses and resulting exposure levels, where known;
- (3) Completed, ongoing and/or planned toxicologic testing in the private sector including detailed experimental protocols and results;
- (4) Results of toxicological studies of structurally related compounds.

Please submit all information in writing June 22, 1992 to Dr. Fung. Any submissions received after the above date will be accepted and utilized if possible.

Dated: May 18, 1992.

Kenneth Olden,

Director, National Toxicology Program.
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